

AUG 23 2002

K022561
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Repair Kit
510(k)

Section 5

Catheter Repair Kit with Replacement Connector

510(k) Summary of Safety and Effectiveness Information
21 CFR 807.92

1. Submitter Information:

Submitter Name: Bard Access Systems, Inc.
[Subsidiary of C. R. Bard, Inc.]
Address: 5425 W. Amelia Earhart Drive
Salt Lake City, UT 84116
Telephone Number: (801) 595-0700, Ext. 4903
Fax Number: (801) 595 5425
Contact Person: Peggy Keiffer
Date of Preparation:

2. Device Name:

Device Name: Catheter Repair Kit with Replacement Connector
Trade Name: Catheter Repair Kit
Common/Usual Name: Catheter Repair Kit
Classification Name: MSD Blood Access Device Accessory
21 CFR 876.5540 Class II
Classification Panel: Gastroenterology and Renal

3. Predicate Device Name:

Device Name: Catheter Repair Kit with Replacement Connector
Trade Name: Catheter Repair Kit
Common/Usual Name: Catheter Repair Kit
Classification Name: MSD Blood Access Device Accessory
21 CFR 876.5540, Class II
Classification Panel: Gastroenterology and Renal

4. Device Description

The Catheter Repair Kit with Replacement Connector is exactly the same as the predicate device.

5. Intended Use

To replace: Cracked or broken female luer lock connectors or repair damaged extension leg where there is a minimum of 4.5 cm of viable extension tubing on the following Vas-Cath catheters:

- Soft-Cell® Long-Term Dual Lumen Catheter
- Opti-Flow® Long-Term Dual Lumen Catheter
- Slim-Cath™ Short-Term Dual Lumen Catheter
- Vaccess® Short-Term Single Lumen Catheter
- Flexxicon® Short-Term Dual Lumen Catheter
- Niagara™ Short-Term Dual Lumen Catheter
- Flexxicon® II Short-Term Dual Lumen Catheter
- HemoGlide™ Long-Term Dual Lumen Catheter

6. Technological Characteristics Summary:

6.1 Does the new device have the same indication statement?

No. The HemoGlide™ Long-Term Dual Lumen catheter is added to the list of repairable catheters in the indication for use and the description of temporary catheter was changed to short-term for labeling consistency.

6.2 Do the differences alter the intended therapeutic/diagnostic/etc. effect? Deciding may consider impact on safety and effectiveness.

No, the intended use is the same. There is only the addition of a catheter trade name added to the list of repairable catheters and a change of the description of temporary catheter to short-term for labeling consistency.

6.3 The new device has the same intended use and may be "Substantially Equivalent."

Yes, the intended use is identical.

6.4 Does the new device have the same technological characteristics, e.g. design, materials, etc.?

Yes, the technological characteristics are exactly the same.

6.5 Are the descriptive characteristics precise enough to ensure equivalence?

Yes.

Conclusion:

Based on FDA's decision tree, the Catheter Repair Kit with Replacement Connector is substantially equivalent to the predicate device, Catheter Repair Kit with Replacement Connector, K011015, concurrence date June 22, 2001.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 23 2002

Ms. Peggy Keiffer
Senior Regulatory Affairs Manager
Bard Access Systems, Inc.
C. R. Bard, Inc.
5425 W. Amelia Earhart Drive
SALT LAKE CITY UT 84116

Re: K022561
Trade/Device Name: Catheter Repair Kit with Replacement
Connector, Model #5587000
Regulation Number: 21 CFR 876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: 78 NFK
Dated: July 31, 2002
Received: August 2, 2002

Dear Ms. Keiffer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section I-D

Catheter Repair Kit with Replacement Connector

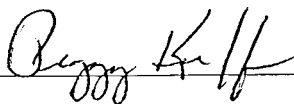
510(k)

INDICATION(S) FOR USE STATEMENT*

I state in my capacity as Senior Regulatory Affairs Manager of Bard Access Systems, that this notification [510(k)] for the following devices, Catheter Repair Kits with Replacement Connectors, are indicated for the following:

To replace: Cracked or broken female luer lock connectors or repair damaged extension where there is a minimum of 4.5 cm of viable extension tubing on the following Vas-Cath catheters: Soft-Cell® Long-Term Dual Lumen Catheter, Opti-Flow® Long-Term Dual Lumen Catheter, Slim-Cath™ Short-Term Dual Lumen Catheter, Vaccess® Short-Term Single Lumen Catheter, Flexxicon® Short-Term Dual Lumen Catheter, Niagara™ Short-Term Dual Lumen Catheter, Flexxicon® II Short-Term Dual Lumen Catheter, HemoGlide™ Long-Term Dual Lumen Catheter.

Signature of 510(k) Submitter:



Printed Name of Submitter:

Peggy Keiffer

Date: 7.16.02

*Suggested language and format to meet the requirements of sections 513(i) of the Federal Food, Drug, and Cosmetic Act, as amended, and sections 807.92(a)(5) and 801.4 of the Code of Federal Regulations, Title 21.

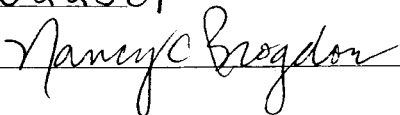
Concurrence of Office of Device Evaluation

510(k) Number

K022561

Division Sign-Off

Office of Device Evaluation



Prescription Use



OR

Over-The-Counter Use

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